

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: THOMAS W. DAVISON

Confirmation No.: 6193

Serial No.: 10/686,154

Examiner: VY Q. BUI

Filed: OCTOBER 15, 2003

Group Art Unit: 3734

Docket No.: 1291.1134102

Customer No.: 28075

Title: METHOD OF SECURING VERTEBRAE

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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By _____


Rachel Gagliardi

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

The rejection of claims 1-10, 13-20, 23-34, 37-42, 44-46, 49-52, 54-56, 59-62, and 64-68 under 35 U.S.C. §102(b) as being anticipated by Graber et al. is in error because Graber et al do not appear to teach the identical invention in as complete detail as recited in the claims.

MPEP 2131 states:

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). ... "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Independent claim 1 recites, in part, "said elongate body having a proximal portion and a distal portion, the distal portion having a rigidity sufficient to provide access to the surgical

location". Graber et al. do not appear to teach such a structure. The Examiner asserts that Graber includes flexible wires 39 that are expandable to provide rigidity for the distal end 50 to access a surgical location. Applicants respectfully disagree. Graber et al. teach "flexible wires 39". Emphasis added; see column 5, lines 12-13. Graber et al. teach an enveloping means 50 including "a flexible web 52 for enveloping the tissue or organ to be removed from a patient." Emphasis added; see column 5, lines 17-20. Graber et al. further teach "web 52 covers the wires 39...web 52 is preferably made from a sturdy water-proof, stain resistant fabric such as treated sail cloth or duck cloth." Emphasis added; see column 5, lines 31 and 40-42. Graber et al. do not appear to teach a structure having a rigidity sufficient to provide access to the surgical location. Applicant submits that the flexible wires 39 and enveloping means 50 made of flexible web or fabric taught by Graber et al. would not inherently have a rigidity sufficient to provide access to a surgical location, as recited in the claim.

If the Examiner is considering the specific elements recited in the claims to be inherent in Graber et al., Applicants submit that there is no basis for such an interpretation. MPEP 2112 IV. states:

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)...

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original).

(Emphasis added). Applicants submit that the claimed system elements, in particular the elongate body having a distal portion having a rigidity sufficient to provide access to the

surgical location, are not necessarily present in Graber et al. It appears the Examiner is asserting that the device of Graber et al. could be modified to achieve the system as claimed, which is not a proper basis for rejection. Graber et al. do not appear to teach each and every element recited in independent claim 1 and the claims dependent thereon. Further, because Graber et al. teach the enveloping means 50 as specifically designed to surround and capture tissue or an organ for removal from the body, Graber et al. appear to teach away from modifying the enveloping means 50 and flexible wires 39 to have a rigidity sufficient to provide access to a surgical location, as claimed.

Regarding independent claim 13, the Examiner asserts that Graber et al. teaches a handle 20 of elongate body 30 and set screw 8 or 9 of support arm 4 as a[n] adjustment mechanism for a user to manually moving the elongate body relative to the support arm. It appears the Examiner has either misread the claims or misinterpreted the reference. Independent claim 13 recites in part, "the elongate support arm having at least one adjustment mechanism configured to move the elongate body relative to the support arm." Applicants submit that the set screws 8 and 9 of Graber do not have the identical structure as the claimed adjustment mechanism configured to move the elongate body relative to the support arm. Graber et al. specifically teach, "the tissue and organ extractor 10 is locked into place by set screws 8 and 9." See column 6, lines 38-39. Graber et al. thus appears to teach set screws 8 and 9 as a locking mechanism, not an adjustment mechanism configured to move the extractor 10, as asserted by the Examiner. Graber et al. thus do not appear to teach each and every element recited in independent claim 13 and the claims dependent thereon.

Regarding independent claim 23, the Examiner asserts that because cannula 4 of Graber is a 3-dimensional structure, it meets the claim limitations. Applicants respectfully disagree. As shown in Fig. 4 of Graber et al., the cannula 4 appears to extend along, rather than transverse to, an axis defined along the passage of the extractor 10. Graber et al. thus cannot be seen to anticipate the structure of independent claim 23, or the claims dependent thereon.

Regarding independent claim 26, the Examiner asserts that support arm 5 of Graber is coupled to support arm 4, with the parenthetical "formed a pair to or combined to" as the interpretation of "coupled to". Applicants respectfully disagree. MPEP 2111 states:

The broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. *In re Cortright*, 165 F.3d 1353, 1359, 49 USPQ2d 1464, 1468 (Fed. Cir. 1999)

Emphasis added. Applicants submit that the Examiner's interpretation of "coupled to" as meaning "formed a pair to or combined to" is inconsistent with the specification and also inconsistent with the interpretation that those skilled in the art would reach. The rejection is thus in error. Graber et al. appear to teach a system in which separate, non-coupled cannulas 4 and 5 are used, with the extractor 10 being inserted through one cannula 4, and a laparoscope being inserted through a auxiliary cannula 5. Thus, even if one were to equate the cannulas 4 and 5 of Graber et al. with the claimed first and second support arms, the claimed structure is distinguished from Graber et al.

Regarding independent claim 37, the Examiner asserts that "Graber-'647's support arm 4 supports elongate body 10 and supports "assists" additional viewing device in a medical procedure. The viewing device includes a handle as an adjustment mechanism for moving the viewing device in a motion generally parallel to a longitudinal axis of the elongate body as recited in the claims." The Examiner has not provided any indication of what element in Graber is interpreted as a "viewing device". Graber et al. appear to teach a cannula 4 for supporting the extractor 10, and a separate, auxiliary cannula 5, for supporting an additional device such as a laparoscope. Graber et al. thus appear to teach separate supports (4 and 5) for the extractor and a laparoscope, but do not appear to teach a support arm configured to support both an elongate body and an additional device, as is recited in the claim. Graber et al. thus cannot be seen to teach each and every element of the structure recited in independent claim 37 or the claims dependent thereon.

Regarding independent claim 62, the Examiner asserts that the viewing device of Graber is considered as operably coupled with the elongate body because the viewing device and the elongate body are operable and used together in a medical operation. Applicants respectfully disagree. As discussed above, MPEP 2111 states that the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach. Applicants submit that those skilled in the art would not consider two separate devices used separately in a medical operation to be operably coupled. Graber et al.

teach separate cannulas 4 and 5 and thus cannot be seen to anticipate the system recited in claim 62 or the claims dependent thereon.

The rejection of claims 26, 27, 30-31, 37, 40-41, and 43 under 35 U.S.C. §102(e) as being anticipated by Bonutti is in error because Bonutti does not teach each and every element of the claims. The Examiner asserts that Bonutti shows first and second support arms 20, 30 for supporting a viewing device as recited in the claims. Applicants do not understand this rejection. Bonutti teach a retractor body 12 and a nut 16 for receiving the body, the body having a widened distal end portion 20, and the nut having a body 30. See column 4, lines 39-58 and Fig. 2. Bonutti does not appear to teach a view device supported by the nut body 30, as asserted by the Examiner. Bonutti do not appear to teach the identical structure as recited in the claims, thus the rejection is in error.

The rejection of claims 11-12, 21-22, 35-36, 47-48, and 57-58 under 35 U.S.C. §103(a) as being unpatentable over Graber et al. is in error because Graber et al. fail to teach or suggest the elements of the independent claims as discussed above. Further, the Examiner has not provided any articulated reasoning with rational underpinning to support the conclusion of obviousness.

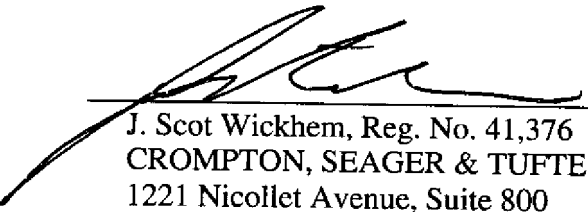
Reexamination and reconsideration are respectfully requested. It is respectfully submitted that the claims are now in condition for allowance.

Respectfully submitted,

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By his attorney,

Date: August 14, 2008


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